REMARKS

Claims 1-38 are pending in the present application. Entry of the above amendments is earnestly solicited. An early and favorable first action on the merits is earnestly solicited.

A marked-up version of the claims showing all changes is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D. (Reg. 40,069) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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MARKED-UP VERSION SHOWING CHANGES

The claims have been amended as follows:

1. (Amended) A method of determining an analyte in a sample comprising the steps of:

a) contacting the sample with a specified amount of a receptor which binds specifically to the analyte to form an analyte/receptor complex, said specified amount of receptor being in excess of that required to bind all analyte in the sample,

b) isolating on a solid phase a specified fraction of the amount of receptor contacted with the analyte, including analyte/receptor complex and unreacted receptor,

c) detecting the amount of analyte/receptor complex in said isolated specified fraction, and

d) from the detected amount <u>of</u> analyte/receptor complex, determining the concentration of analyte in the sample.

4. (Amended) The method according to [claims 1 to 3]<u>claim 1 or 2</u>, wherein isolating said specified fraction of the amount of receptor contacted with the sample on the solid phase comprises providing a solid phase having binding sites for the receptor, and after contacting the sample, or an aliquot thereof, with a liquid

phase containing the receptor, binding said specified fraction of receptor to the solid phase.

7. (Amended) The method according to [claims 1 to 3]claim 1 or 2, wherein isolating said specified fraction of the amount of receptor on the solid phase comprises contacting the sample with a specified amount of receptor, a specified fraction of which amount is immobilized to said solid phase and the remaining amount of receptor being in a liquid phase.

8. (Amended) The method according to [any one of claims 1 to 6]claim 1, wherein in step c) the analyte/receptor complex is detected by a labeled detection reagent which binds specifically to the analyte.

10. The method according to [any one of the preceding claims] claim 1, wherein in step c) the analyte/receptor complex is detected by a labelled detection reagent which binds specifically to the analyte.

11. (Amended) The method according to [any one of the proceeding claims]claim 1, wherein the ratio between said isolated fraction of the amount of active analyte-binding receptor and the

total amount of active analyte-binding receptor contacted with the sample is in the range of from about 1:2 to about 1:1000[, preferably from about 1:5 to 1:100, particularly no more than about 1:20].

12. (Amended) The method according to [any one of the proceeding claims]claim 1, wherein said solid phase binding sites for the receptor are immobilized in a reaction zone of flow matrix[, preferably a lateral flow matrix, such as a membrane strip].

13. (Amended) The method according to [any one of the proceeding claims]claim 1, wherein the receptor is an antibody or immunoreactive fragment thereof.

14. (Amended) The method according to [any one of the proceeding claims]claim 8, wherein the detection reagent is an antibody or immunoreactive fragment thereof.

15. (Amended) The method according to [any one of the proceeding claims]claim 8, wherein the detection reagent is labelled by a fluorophore or chromophore.

16. (Amended) The method according to [any one of the proceeding claims]claim 7, wherein the specific binding pair is biotin-avidin or biotin-strepavidin.

17. (Amended) The method according to [any one of the proceeding claims]claim 1, wherein the sample is an undiluted serum sample.

18. (Amended) The method according to [any one of claims 1 to 16]claim 1, wherein the sample is an undiluted whole blood sample.

20. (Amended) The test kit according to claim 19, wherein the ratio between the receptor-binding capacity of ligand immobilized on the solid phase and the ligand-binding capacity of the analyte-specific receptor substance is in the range of from about 1:2 to about 1:1000[, preferably from about 1:5 to 1:100, particularly no more than about 1:20].

21. (Amended) The test kit according to claim 19 or 20, further comprising a lateral flow membrane strip having said receptor-binding ligand immobilized in or on a reaction zone of the membrane and having said analyte-binding receptor substance

dissolvably pre-deposited in or on the membrane upstream of the reaction zone.

23. (Amended) The test kit according to claim 22, wherein the ratio between the amount of ligand-binding analyte-specific receptor and the total amount of analyte-specific receptor is in the range of from about 1:2 to about 1:1000[, preferably from about 1:5 to 1:100, particularly no more than about 1:20].

24. (Amended) The test kit according to claim 22 or 23, further comprising a lateral flow membrane strip having said receptor-binding ligand immobilized in or on a reaction zone of the membrane and having said analyte-binding receptor substance dissolvably pre-deposited in or on the membrane upstream of the reaction zone.

26. (Amended) The test kit according to claim 25, wherein the ratio between said second amount of analyte-binding receptor substance immobilized to the solid phase, and the sum of said first and second amounts of analyte-binding receptor substance is in the range of from about 1:2 to about 1:1000[, preferably from about 1:5 to 1:100, particularly no more than about 1:20].